

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
23-R-0012

CUSTOMER NO.
286

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

NOV 29 2006

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

GLAXO SMITH KLINE
709 SWEDELAND ROAD, P.O. BOX 1539
KING OF PRUSSIA, PA 19406
(610) 270-4800

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	594	356	18	968
5. Cats	24	17	102	0	119
6. Guinea Pigs	216	914	581	82	1577
7. Hamsters	12	20	165	0	185
8. Rabbits	78	137	1493	0	1630
9. Non-Human Primates	12	336	723	13	1072
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Ferrets	16	0	0	65	65

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

b6, b7c

DATE SIGNED

22 Nov
2006

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Explanation of Animals Listed in Column E
2005-2006 USDA Annual Report for Registration Number 23-R-0012

Dogs

Eighteen (18) dogs are listed in Column E.

GLP Dose Range Study

Two (2) dogs were part of a Safety Assessment study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Nonclinical Laboratory Studies, 21 CFR Part 58. The dogs were used on a dose range finding study. The first dose created unanticipated neurological signs (e.g. animals exhibited tremors, showed altered consciousness) in a male and a female dog. Clinical signs diminished over the short half-life of the drug. It was decided to decrease the dose for the next scheduled dosing and re-dose the same 2 dogs. After the second dose both dogs showed similar neurological signs. The animals were then euthanized immediately. Treating the dogs with anesthetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

Osteoarthritis Study

Sixteen (16) dogs were assigned to an osteoarthritis study. Dogs on study underwent intra-articular sampling and injection while under anesthesia. The animals were monitored at least twice daily. Some of the dogs exhibited lameness after the procedure but usually for only a few hours. No pain relieving drugs could be given because the drugs affect cytokine production and/or inflammation that would interfere with interpretation of data.

Ferrets

Sixty five (65) ferrets are listed in Column E.

Studies for development of novel anti-emetic compounds for the treatment of chemotherapy induced emesis

Sixty five (65) ferrets were involved in studies to evaluate novel anti-emetic compounds. Animals were given novel anti-emetic compounds plus vehicle then given a known agent that causes vomiting and closely monitored. Animals showed mild to moderate signs of sedation (quiet and sleeping) within the first few hours of dosing. Signs of emesis were not seen routinely. All animals were euthanized shortly after the end of the 6 hour studies. Known anti-emetic compounds or analgesics were not given because of interference with study results.

Guinea Pigs

Eighty two (82) guinea pigs are listed in Column E.

Studies developing novel antimicrobial therapies for infectious pneumonia

Forty two (42) guinea pigs were assigned to a study evaluating treatments for infectious pneumonia. Animals on study were anesthetized and infected with bacteria that were placed into one lung by non-surgical intra-tracheal instillation. Animals were then divided into control and drug-treated groups and drug treated animals started therapy within 24 hours post-infection. All guinea pigs on this study continued to eat and none showed signs of respiratory distress. Some animals had a weight loss of approximately 10%. The guinea pigs were euthanized on the 3rd day post-infection. Analgesics could not be used because of interference with disease development and study results.

Studies exposing guinea pigs to cigarette smoke to develop a pulmonary disease model

Forty (40) guinea pigs were exposed to cigarette smoke for 15, 30, 60 or 120 minutes daily for several days. The animals were weighed and observed daily. None of the animals showed signs of respiratory distress. The guinea pigs could not be given analgesics or treated for respiratory abnormalities since this would interfere with development of this model.

Nonhuman Primates

Thirteen (13) monkeys are listed in Column E.

Studies evaluating thyroid hormone metabolism and pharmacokinetics

Thirteen (13) monkeys were used on a study to evaluate thyroid hormone metabolism and pharmacokinetics of novel compounds used to treat thyroid hormone abnormalities. Animals were required to fast at least 24 hours based on published findings that a 24-hour fast was necessary to get the required baseline levels of thyroid hormone for the study. Blood was collected from the animals after the 24 hour time point. No animals were observed with abnormal clinical signs.